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First Named Inventor

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Art Unit

1743

Examiner Name

Samuel P. Siefke

Attorney Docket Number

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David G. Parkhurst

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David G. Parkhurst, Reg. No. 29,422

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of  
**JAMES E. PARKER**  
Serial No. 09/752,712  
Filed: December 28, 2000  
For: DRUG TEST KIT

Examiner: Samuel P. Siefke  
Group Art Unit: 1743  
Docket No.: VTECH-48514  
February 5, 2007  
Los Angeles, California 90045

AMENDED APPEAL BRIEF

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This Amended Appeal Brief is being filed in response to the Notification of Non-Compliant Appeal Brief dated January 8, 2007, and setting a period of one month or thirty days from the mailing of the Notification, whichever is longer. A Notice of Appeal was filed on August 4, 2006, from the final rejection dated March 7, 2006 finally rejecting claims 15, 16, 18, 20, 21 and 23. An Appeal Brief was filed on October 4,

2006, within the term provided as permitted under 37 C.F.R. § 1.192(a). This Amended Appeal Brief corrects the concise explanation of the subject matter defined in the independent claims and provides the heading for that section as prescribed in 37 CFR 41.37(c)(1)(v).

### **I. REAL PARTY IN INTEREST**

The real party in interest is MODERN OPTICS, INC. This application was assigned by the inventor, JAMES E. PARKER to MODERN OPTICS, INC., by an assignment executed December 5, 2000, which was recorded by the Patent Office on December 28, 2000, at reel 011703, frame 0977.

### **II. RELATED APPEALS AND INTERFERENCES**

None.

### **III. STATUS OF CLAIMS**

Claims 15, 16, 18, 20, 21 and 23 remain pending, and were finally rejected in an Office Action dated March 7, 2006. Claims 1-14, 17, 19, 22 and 24-31 have been cancelled.

### **IV. STATUS OF AMENDMENTS**

The claims were most recently amended in the Amendment of December 9, 2005, which was entered.

## **V. SUMMARY OF CLAIMED SUBJECT MATTER**

The embodiment of the invention currently claimed in independent Claims 15 and 20 is depicted in Figs. 4-5, and is described in detail in the specification at page 8, line 17, to page 9, line 9.

As is recited in independent Claim 15, the **assaying apparatus** (60, Fig. 4) for collecting and analyzing a liquid sample for an analyte in the liquid sample includes a **container** (62, Fig. 4) having an **interior sample chamber** (64, Fig. 4) with a liquid sample space, and the **container** (62, Fig. 4) has a surface defining an opening in communication with the **interior sample chamber** (64, Fig. 4). The **assaying apparatus** (60, Fig. 4) also includes a **cap** (68, Figs. 4 and 5) adapted to be placed on the **container** (62, Fig. 4) opening for closing the **container** (62, Fig. 4) opening and sealing the **container** (62, Fig. 4). An **assay strip** (70, Fig. 5) is disposed in the **cap** (68, Figs. 4 and 5), and the **assay strip** (70, Fig. 5) has an **assay region** (72, Fig. 5) disposed in the **cap** (68, Figs. 4 and 5) for indicating the presence or absence of an analyte in a liquid sample placed in the liquid sample space of the **interior sample chamber** (64, Fig. 4). The **cap** (68, Figs. 4 and 5) includes a **separator member** (84, Fig. 5) disposed between the **assay strip** (70, Fig. 5) and the **interior sample chamber** (64, Fig. 4) for separating the liquid sample space from the **assay region** (72, Fig. 5) of the **assay strip** (70, Fig. 5). A **wick** (78, Fig. 4) is mounted to the **cap** (68, Figs. 4 and 5) and extends into the liquid sample space of the **interior sample chamber** (64, Fig. 4) when the **cap** (68, Figs. 4 and 5) is placed on the **container** (62, Fig. 4). The **wick** (78, Fig. 4) is in fluid

communication with the **assay strip** (70, Fig. 5) for conducting a portion of the liquid sample from the **interior sample chamber** (64, Fig. 4) to the **assay region** (72, Fig. 5) of the **assay strip** (70, Fig. 5). An **annular bridging wick piece** (80, Fig. 5) is connected between the **wick** (78, Fig. 4) and the **assay strip** (70, Fig. 5) and in fluid communication with the **wick** (78, Fig. 4) and the **assay strip** (70, Fig. 5), and in immediate contact with the **assay strip** (70, Fig. 5) for conducting the liquid sample from the **wick** (78, Fig. 4) to the **assay strip** (70, Fig. 5).

As is recited in independent Claim 20, the **assaying apparatus** (60, Fig. 4) for collecting and analyzing a liquid sample for the presence or absence of a plurality of analytes in the liquid sample includes a **container** (62, Fig. 4) having an **interior sample chamber** (64, Fig. 4) with a liquid sample space, and the **container** (62, Fig. 4) has a surface defining an opening in communication with the **interior sample chamber** (64, Fig. 4). The **assaying apparatus** (60, Fig. 4) includes a **cap** (68, Figs. 4 and 5) adapted to be placed on the **container** (62, Fig. 4) opening for closing the **container** (62, Fig. 4) opening and sealing the **container** (62, Fig. 4). A plurality of **assay strips** (70, Fig. 5) are disposed in the **cap** (68, Figs. 4 and 5), with each **assay strip** (70, Fig. 5) having an **assay region** (72, Fig. 5) disposed in the **cap** (68, Figs. 4 and 5) for indicating the presence or absence of one of a plurality of analytes in a liquid sample placed in the liquid sample space of the **interior sample chamber** (64, Fig. 4). The **cap** (68, Figs. 4 and 5) includes a **separator member** (84, Fig. 5) disposed between the **assay strips** (70, Fig. 5) and the **interior sample chamber** (64, Fig. 4) for separating the liquid sample space from the **assay region** (72, Fig. 5) of the **assay strips** (70, Fig. 5). A **wick** (78, Fig.

4) is mounted to the **cap** (68, Figs. 4 and 5) and extends into the liquid sample space of the **interior sample chamber** (64, Fig. 4) when the **cap** (68, Figs. 4 and 5) is placed on the **container** (62, Fig. 4). The **wick** (78, Fig. 4) is in fluid communication with the **assay strips** (70, Fig. 5) for conducting a portion of the liquid sample from the **interior sample chamber** (64, Fig. 4) to the **assay region** (72, Fig. 5) of the **assay strips** (70, Fig. 5). An **annular bridging wick piece** (80, Fig. 5) is connected between the **wick** (78, Fig. 4) and the **assay strips** (70, Fig. 5) and in fluid communication with the **wick** (78, Fig. 4) and the **assay strips** (70, Fig. 5) and in immediate contact with the **assay strips** (70, Fig. 5) for conducting the liquid sample from the **wick** (78, Fig. 4) to the **assay strips** (70, Fig. 5).

## **VI. ISSUES ON APPEAL**

### **A. THE EXAMINER'S REJECTIONS**

In the final Office Action of March 7, 2006, Claims 18 and 23 were objected to under 37 CFR 1.75(c) as being of improper dependent form for failing to limit the subject matter of a previous claim. The Examiner indicated that Claims 15 and 20 have limitations of an assay strip comprising a wicking material.

Claims 15-16, 18, 20, 21 and 23 were rejected under 35 U.S.C. 103(a) on the grounds of obviousness from U.S. Patent No. 6,627,152 to Wong in view of U.S. Patent No. 6,168,758 to Forsberg et al. and U.S. Patent No. 5,501,837 to Sayles. Wong was cited as disclosing a wick mounted to the cap and extending the liquid sample space of the interior sample chamber when the cap is placed on the container. Forsberg et al. was

cited as disclosing wick pads 4 in contact with wicks 3 and that are used to transfer sample liquid 30 from the reservoir 18 by the wicks 3 to test strips 5. The Examiner acknowledged that Wong does not teach using an "annular" bridging member to link the assay strip to the wicking member, but argued that the wick pads 4 of Forsberg et al. constitute an annular bridging wick piece as recited in Claims 15 and 20, and that it would have been obvious to modify Wong to use the wick pads 4 of Forsberg et al. to provide an "annular" bridging wick piece. Sayles was cited as disclosing an annular wick 38 in contact with test strips 32. The Examiner further argued that it would have been obvious to modify Wong to use the absorbent pad 38 of Sayles to provide an "annular" bridging wick piece.

## **B. THE ISSUES FOR DETERMINATION**

In view of the Examiner's rejections and arguments, Appellant respectfully submits that the issues on appeal are as follows:

- 1) Do Claims 15 and 20 recite an assay strip comprising a wicking material?
- 2) Does the prior art cited disclose a wick mounted to the cap of a container and extending into the liquid sample space of the interior sample chamber when the cap is placed on the container, as is recited in Claims 15 and 20?
- 3) Does the prior art cited disclose an annular bridging wick piece connected between a wick and an assay strip or strips in fluid

communication with the wick and the assay strip or strips, and in immediate contact with an assay strip or strips for conducting a liquid sample from the wick to the assay strip or strips, as is recited in Claims 15 and 20?

## **VII. GROUPING OF CLAIMS**

Claims 15-16, 18, 20, 21 and 23 stand or fall together.

## **VIII. ARGUMENTS**

### **A. THE OBJECTION TO CLAIMS 18 AND 23 FOR FAILING TO LIMIT THE SUBJECT MATTER OF A PREVIOUS CLAIM**

#### **1. CLAIM 15 DOES NOT RECITE AN ASSAY STRIP COMPRISING A WICKING MATERIAL**

The Examiner objected to Claim 18 on the grounds that Claim 15 already has limitations for an assay strip comprising a wicking material for conducting the liquid sample from the wick to the assay region of the assay strip. Claim 18 recites "wherein said assay strip comprises wicking material for conducting the liquid sample from said wick to said assay region of said assay strip."

Claim 15 recites "an assay strip disposed in said cap, said assay strip having an assay region disposed in said cap for indicating the presence or absence of an analyte in a liquid sample placed in said liquid sample space of said interior chamber, and said cap including a separator member disposed between said assay strip and said interior sample chamber for separating said liquid sample space from said assay region of said assay strip." Claim 15 does not recite that the assay strip comprises wicking material for conducting the liquid sample from the wick to the assay region of the assay strip, as asserted by the Examiner. It is therefore respectfully submitted that the Examiner's objection to Claim 18 was in error, and that the objection to claim 18 should be withdrawn.

**2. CLAIM 20 DOES NOT RECITE AN ASSAY STRIP**  
**COMPRISING A WICKING MATERIAL**

The Examiner objected to Claim 23 on the grounds that Claim 20 already has limitations for an assay strip comprising a wicking material for conducting the liquid sample from the wick to the assay region of the assay strip. Claim 23 recites "wherein said assay strips comprise wicking material for conducting the liquid sample from said wick to said assay regions of said assay strips."

Claim 20 recites "a plurality of assay strips disposed in said cap, each assay strip having an assay region disposed in said cap for indicating the presence or absence of one of a plurality of analytes in a liquid sample placed in said liquid sample space of said interior chamber, and said cap including a separator member disposed between said assay strips and said interior sample chamber for separating said liquid sample space from said assay region of said assay strip." Claim 20 does not recite that the assay strips comprise wicking material for conducting the liquid sample from the wick to the assay region of the assay strip, as asserted by the Examiner. It is therefore respectfully submitted that the Examiner was in error, and that the objection to claim 23 should be withdrawn.

**B. THE REJECTION OF CLAIMS 15-16, 18, 20, 21 AND 23 AS**

**OBVIOUS**

**1. WONG, FORSBERG ET AL. AND SAYLES DO NOT**  
**DISCLOSE A CAP WITH TEST STRIP END PORTIONS**  
**EXTENDING INTO A CONTAINER INTERIOR SAMPLE**  
**CHAMBER LIQUID SAMPLE SPACE WHEN A CAP IS**  
**PLACED ON THE CONTAINER**

Regarding the rejection of Claims 15-16, 18, 20, 21 and 23, it is respectfully submitted that Wong, Forsberg et al. and Sayles do not teach, disclose or suggest test strip end portions that extend into the liquid sample space of the interior sample chamber when the cap is placed on the container. Claims 15 and 20 recite "a container having an interior sample chamber with a liquid sample space," and "a wick mounted to said cap and extending into said liquid sample space of said interior sample chamber when said cap is placed on said container."

Wong was cited as disclosing a wick that extends into a sample when the cap is on the container, and the Examiner referred to Fig. 8 of Wong. Fig. 8 of Wong shows a vessel 20 with fluid 130 in the vessel, and it is clear that the end portion 122 of each test strip 120 does not extend into the fluid 130 in the vessel. As is illustrated in Fig. 5 of Wong, and as described at column 4, lines 28-40, the end portion 122 of each test strip 120 exits through an exit port 90, and the end portions 122 and the exit ports 90 are surrounded by the rim 92 on the bottom side 78 of the cap. In Wong, the end portions 122 of each test strip do not extend into the liquid sample space 130 of the interior sample chamber 38 when the cap is placed on the container. As is described in Wong at column 3 line 50, to column 4, line 44, the carrier 50 is provided to bring liquid sample up to the test strip end portions 122, because the test strip end portions do not extend into the liquid sample space of the interior sample chamber when the cap is placed on the container.

Forsberg et al. was not cited as disclosing a wick that extends into a sample when the cap is on the container. Figs. 3 and 16 of Forsberg et al. show a container 25, 200,

with a liquid sample 30, 202, with wicks 3, 120 in the cap and separated from the liquid sample space in the container by the base of a reservoir 18, and a wick chamber 118.

Sayles was not cited as disclosing a wick that extends into a sample when the cap is on the container. Sayles discloses reagent strips 32 that are directly in contact with the fluid supply through the test chambers 34 and windows 24, 26, and does not disclose wick that extends into a sample when the cap is on the container.

It is therefore respectfully submitted that Wong, Forsberg et al. and Sayles, taken either individually or in combination, do not teach, disclose or suggest wick mounted to the cap of a container and extending into the liquid sample space of the interior sample chamber when the cap is placed on the container, as is recited in Claims 15 and 20.

**2. THE PRIOR ART CITED DOES NOT DISCLOSE AN ANNULAR BRIDGING WICK PIECE ADJACENT TO AND IN FLUID COMMUNICATION WITH A WICK, AND IN IMMEDIATE CONTACT WITH AN ASSAY STRIP OR STRIPS FOR CONDUCTING A LIQUID SAMPLE FROM THE WICK TO THE ASSAY STRIP OR STRIPS**

Claim 15 recites "an annular bridging wick piece connected between said wick and said assay strip in fluid communication with said wick and said assay strip and in immediate contact with said assay strip for conducting the liquid sample from said wick to said assay strip." Claim 20 similarly recites "an annular bridging wick piece connected

between said wick and said assay strips in fluid communication with said wick and said assay strips and in immediate contact with said assay strips for conducting the liquid sample from said wick to said assay strips."

The Examiner acknowledged that Wong does not teach using an "annular" bridging member to link the assay strip to the wicking member. The Examiner argued that Forsberg et al. discloses wick pads 4 that constitute an annular bridging wick piece as recited in Claims 15 and 20, and that it would have been obvious to modify Wong to use the wick pads 4 of Forsberg et al. to provide an "annular" bridging wick piece. The Examiner cited Webster's Ninth New Collegiate Dictionary as defining "annular" as "of, relating to, or forming a ring." The Examiner did not assert that the wick pads 4 of Forsberg et al. form a "ring," and did not assert what part of the definition of "ring" applied to the four spaced apart wick pads 4 of Forsberg et al. Fig. 2 of Forsberg et al. discloses four wick rounded flattened wick pads arranged in a squared pattern. The Examiner does not assert that the squared pattern of wick pads forms a ring, but indicates that the wick pads 4 of Forsberg et al. perform the same function as an annular bridging wick piece. However, Fig. 2 clearly shows that the four wick pads 4 of Forsberg et al. would connect separately with four test strips 5, so that the four different wick pads 4 can convey liquid sample non-uniformly, and with differing effectiveness, whereas the annular bridging wick piece 78 of the present invention will convey liquid sample uniformly and with the same effectiveness, because the annular bridging wick piece 78 does form a ring. Therefore the four wick pads 4 of Forsberg et al. do not perform the same function as the annular bridging wick piece of the present invention, and that

Forsberg et al. does not teach, disclose or suggest an annular bridging wick piece connected between a wick and an assay strip in fluid communication with the wick and the assay strip and in immediate contact with the assay strip for conducting the liquid sample from the wick to the assay strip, as is claimed.

Sayles was cited as disclosing an annular wick 38 in contact with test strips 32, and the Examiner argued that it would have been obvious to modify Wong to use the absorbent pad 38 of Sayles to provide an "annular" bridging wick piece. Sayles discloses an absorbent pad 38 which is annular that is not connected between a wick and an assay strip in fluid communication with the wick and the assay strip and in immediate contact with the assay strip for conducting the liquid sample from the wick to the assay strip, but instead aids in drawing fluid from protruding ends of reagent strips along the lengths of the reagent strips by capillary action. Placing the annular wick 38 of Sayles at the ends of the test strips 120 of Wong to draw fluid from the test strips of Wong would not result in the present invention. Placing the annular wick 38 of Sayles at the other ends of the test strips 120 of Wong would serve no function, because Wong discloses at column 4, lines 33-36, that "pads disposed at the end 122 of the strip 120" already "contact the middle portion 125 of the strip 120, such that the strip functions properly." These pads disposed at the end 122 of the strip 120 of Wong are shown in Fig. 4 to be the wicks that extend into a fluid sample when the fluid sample is lifted up by the carrier 50, and these pads disposed at the end 122 of the strip 120 of Wong directly wick fluid to the test strips 120, so that an annular bridging wick piece would serve no function in Wong.

It is therefore respectfully submitted that Wong, Forsberg et al. and Sayles, taken either individually or in combination, do not teach, disclose or suggest an annular bridging wick piece connected between a wick and an assay strip in fluid communication with the wick and the assay strip and in immediate contact with the assay strip for conducting the liquid sample from the wick to the assay strip, as is recited in Claims 15 and 20.

#### **IX. CONCLUSION**

For the foregoing reasons, it is submitted that the Examiner's objections to Claim 18 and 23 were erroneous; that the present invention as claimed is not rendered obvious from U.S. Patent No. 6,627,152 to Wong in view of U.S. Patent No. 6,168,758 to Forsberg et al. and U.S. Patent No. 5,501,837 to Sayles, and that the Examiner's rejections of 15-16, 18, 20, 21 and 23 were therefore erroneous.

Appellant respectfully requests reversal of the objections to Claims 18 and 23 and the rejection of 15-16, 18, 20, 21 and 23.

The fee for the appeal brief was previously provided with the filing of the appeal brief on October 4, 2006. Please charge any additional fee that may be required to our Deposit Account No. 06- 2425.

Respectfully submitted,

FULWIDER PATTON LLP

By:   
David G. Parkhurst  
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## **X. APPENDIX**

### **CLAIMS ON APPEAL:**

15. Assaying apparatus for collecting and analyzing a liquid sample for an analyte in the liquid sample, the apparatus comprising:

    a container having an interior sample chamber with a liquid sample space, said container having a surface defining an opening in communication with said interior sample chamber;

    a cap adapted to be placed on said container opening for closing said container opening and sealing said container;

    an assay strip disposed in said cap, said assay strip having an assay region disposed in said cap for indicating the presence or absence of an analyte in a liquid sample placed in said liquid sample space of said interior chamber, and said cap including a separator member disposed between said assay strip and said interior sample chamber for separating said liquid sample space from said assay region of said assay strip;

    a wick mounted to said cap and extending into said liquid sample space of said interior sample chamber when said cap is placed on said container, said wick being in fluid communication with said assay strip for conducting a portion of the liquid sample from said interior chamber to said assay region of said assay strip; and

an annular bridging wick piece connected between said wick and said assay strip in fluid communication with said wick and said assay strip and in immediate contact with said assay strip for conducting the liquid sample from said wick to said assay strip.

16. The assaying apparatus of Claim 15, further comprising a transparent cover over said assay strip permitting observation of the results of the assay.

18. The assaying apparatus of Claim 15, wherein said assay strip comprises wicking material for conducting the liquid sample from said wick to said assay region of said assay strip.

20. Assaying apparatus for collecting and analyzing a liquid sample for the presence or absence of a plurality of analytes in the liquid sample, the apparatus comprising:

a container having an interior sample chamber with a liquid sample space, said container having a surface defining an opening in communication with said interior sample chamber;

a cap adapted to be placed on said container opening for closing said container opening and sealing said container;

a plurality of assay strips disposed in said cap, each assay strip having an assay region disposed in said cap for indicating the presence or absence of one of a plurality of analytes in a liquid sample placed in said liquid sample space of said interior chamber, and said cap including a separator member disposed between said assay strips and said interior sample chamber for separating said liquid sample space from said assay region of said assay strip;

a wick mounted to said cap and extending into said liquid sample space of said interior sample chamber when said cap is placed on said container, said wick being in fluid communication with said assay strip for conducting a portion of the liquid sample from said interior chamber to said assay region of said assay strip; and

an annular bridging wick piece connected between said wick and said assay strips in fluid communication with said wick and said assay strips and in immediate contact with said assay strips for conducting the liquid sample from said wick to said assay strips.

21. The assaying apparatus of Claim 20, further comprising a transparent cover over said assay strips permitting observation of the results of the assays.

23. The assaying apparatus of Claim 20, wherein said assay strips comprise wicking material for conducting the liquid sample from said wick to said assay regions of said assay strips.

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